

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on November 28, 2005


Jacquelyn R. Bolin

1AP10 Rec PCT/PTO 02 DEC 2005

#7



Attorney Docket No. CSU-001M

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of :

E. D. LEPHART et al. :

Serial No.: 10/533,045 :

I.A. Filed: 03/29/2003 :

Confirmation No.: 6027

Group Art Unit: 1617

USE OF EQUOL FOR TREATING ANDROGEN-MEDIATED DISEASES

INFORMATION DISCLOSURE STATEMENT
PURSUANT TO 37 CFR 1.56, 1.97 and 1.98

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR §§1.56, 1.97 and 1.98, Applicant request the Examiner to make of record the documents listed on the attached PTO/SB/08 form in connection with examination of the above-identified patent application. As provided in §1.97(g), no representation is made or intended that a thorough art search was made. As provided in 37 C.F.R. §1.97(h), this Information Disclosure Statement does not constitute an admission of any kind, and specifically is not an admission that the documents listed on attached form PTO/SB08 are, or are considered to be, material to the patentability of the above-identified patent application, as defined in 37 C.F.R. §1.56(b). In accordance with 37 C.F.R. §1.98(a)(2), Applicants are submitting copies of foreign patent documents and non-patent literature.

Applicants also respectfully request the Examiner to consider and make of record the co-pending applications listed on the attached page.


This information disclosure statement is being submitted under 37 C.F.R. §1.97(b)(3). Applicants have not received an Office Action on the merits in the present application. Therefore, no fee is believed to be due.

This submission does not represent that a search has been made or that no closer art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and Applicant determines that the cited documents do not constitute "prior art" under United States law, Applicant reserves the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicant further reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

Respectfully submitted,

For: E. D. LEPHART et al.

By 

Daniel F. Nesbitt
Attorney for Applicant
Registration No. 33,746
(513) 229-0383
Customer Number 38155

November 28 2005

#7

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

DEC 02 2005

3 Sheet

1

of

7

Complete if Known

Application Number 10/533,045

I.A. Filing Date 03/29/2003


First Named Inventor LEPHART et al.

Art Unit 1617

Examiner Name

Attorney Docket Number CSU-001M

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)				
7PEZ/		US	4,390,559	06/28/1983	Zilliken	
		US	4,814,346	03/21/1989	Albert et al.	
		US	5,141,746	08/25/1992	Fleury et al.	
		US	5,352,384	10/04/1994	Shen	
		US	5,424,331	06/13/1995	Shlyankevich	
		US	5,498,631	03/12/1996	Gorbach et al.	
		US	5,523,087	06/04/1996	Shlyankevich	
		US	5,726,034	03/10/1998	Bryan et al.	
		US	5,733,926	03/31/1998	Gorbach	
		US	5,804,234	09/08/1998	Suh et al.	
		US	5,830,887	11/03/1998	Kelly	
		US	5,849,798	12/15/1998	Charpentier et al.	
		US	5,855,892	01/05/1999	Potter et al.	
		US	5,942,539	08/24/1999	Hughes, Jr. et al.	
		US	5,952,374	09/14/1999	Clarkson et al.	
		US	5,958,946	09/28/1999	Styczynski et al.	
		US	5,990,291	11/23/1999	Waggle et al.	
		US	6,004,558	12/21/1999	Thurn et al.	
		US	6,020,471	02/01/2000	Johns et al,	
		US	6,054,636	04/25/2000	Fader	
		US	6,060,070	05/09/2000	Gorbach	
		US	6,083,526	07/04/2000	Gorbach	
		US	6,146,668	11/14/2000	Kelly et al.	
		US	6,159,959	12/12/2000	Miller	
		US	6,194,450 B1	02/27/2001	Charpentier et al.	
		US	6,242,594 B1	06/05/2001	Kelly	
		US	6,258,856	07/10/2001	Chamberlain et al.	
		US	6,326,366 B1	12/04/2001	Potter et al.	
		US	6,340,703 B1	01/22/2002	Kelly	
		US	6,375,994 B1	04/23/2002	Paul et al.	
		US	6,448,237 B1	09/10/2002	Kelly	
		US	6,455,032 B1	09/24/2002	Kelly et al.	
		US	6,497,906 B1	12/24/2002	Kelly	
		US	6,509,043	01/21/2003	Hoie	
		US	6,518,301 B1	02/11/2003	Barlaam et al.	
		US	6,544,566	04/08/2003	Waggle et al.	
		US	6,562,380 B1	05/13/2003	Kelly	
		US	6,565,864 B2	05/20/2003	Pillai et al.	
		US	6,599,536 B1	07/29/2003	Kelly	
		US	6,628,543	10/28/2003	Kang et al.	
		US	6,642,212 B1	11/04/2003	Kelly	
		US	6,649,648 B1	11/18/2003	Kelly et al.	
		US	6,716,424	04/06/2004	Uchiyama et al.	
		US	2002/0001565 A1	01/03/2002	Shapiro	


INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Complete if Known

Sheet	2	of	7	Application Number	10/533,045
				I.A. Filing Date	03/29/2003
				First Named Inventor	LEPHART et al.
				Art Unit	1617
				Examiner Name	
				Attorney Docket Number	CSU-001M

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)				
/PEZ/		US	2002/0019377 A1	02/14/2002	Jenkins et al.	
		US	2002/0035074 A1	03/21/2002	Kelly	
		US	2002/0160064	10/31/2002	Zulli et al.	
		US	2002/0198248 A1	12/26/2002	Kelly et al.	
		US	2003/0018060 A1	01/23/2003	Kelly et al.	
		US	2003/0027772 A1	02/06/2003	Breton	
		US	2003/0059384 A1	03/27/2003	Kelly et al.	
		US	2003/0078214 A1	04/24/2003	Kelly	
		US	2003/0219499 A1	11/27/2003	Kelly	
		US	Re. 34,457	11/30/1993	Okamoto et al.	
		US	2003/0027772 A1	02/06/2003	Breton	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³	Number ⁴ -Kind Code ⁵ (if known)				
/PEZ/		Japan	H02-124883	05/14/1990	Kitasato Institute	Partial English Translation	
		Australia	AU 20006896 A4	05/11/2000	Praxis Pharmaceuticals Australia Pty Ltd.	Abstract	
		WO	93/23069	11/25/1993	Kelly, Graham, Edmund		
		WO	94/23716	10/27/1994	Tufts University School of Medicine		
		WO	96/10341	04/11/1996	Van Haaster, Joseph, Nicolas		
		WO	97/06273	02/20/1997	Fermalogic, Inc.		
		WO	98/21946 A1	05/28/1998	Internutria, Inc.		
		WO	98/26784 A1	06/25/1998	University of Sydney		
		WO	99/49851 A1	10/07/1999	Bioresponse L.L.C.		
		WO	98/48790	11/05/1998	Anticancer, Inc.-		
		WO	99/61028 A1	12/02/1999	Gorbach		
		WO	00/13661 A1	03/16/2000	Avon Products Inc.		
		WO	00/30663 A1	06/02/2000	Nutri Pharma ASA		
		WO	00/41491 A2	07/20/2000	Nutrahealth Ltd.		
		WO	00/49009 A1	08/24/2000	Novogen Research Pty. Ltd.		
		WO	00/62774 A1	10/26/2000	Board of Trustees, Southern Illinois Univ.		
		WO	00/62765 A2	10/26/2000	Astrozeneca		
		WO	02/03976 A2	01/17/2002	American Home Prod. Corp.		
		WO	02/03977 A2	01/17/2002	American Home Prod. Corp.		
		WO	02/11675 A2	02/14/2002	Zelickson, M.,D., Brian, D.		
		WO	02/03992 A2	01/17/2002	American Home Prod. Corp.		
		WO	02/053108 A2	07/11/2002	Unilever PLC		
		WO	02/062367 A1	08/15/2002	Metagenics, Inc.		
		WO	02/087517	11/07/2002	Beiersdorf AG	Abstract	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Complete if Known

<div>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</div> <div>(use as many sheets as necessary)</div>				<i>Complete if Known</i>	
				Application Number	10/533,045
				I.A. Filing Date	03/29/2003
				First Named Inventor	LEPHART et al.
				Art Unit	1617
				Examiner Name	
				Attorney Docket Number	CSU-001M
Sheet	3	of	7		

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³	Number ⁴ -Kind Code ⁵ (if known)				
/PEZ/ ↓		WO	02/089757	11/14/2002	Beiersdorf AG	Abstract	
		WO	04/022023	03/18/2004	Novogen Research		
		WO	04/026274	04/01/2004	Novogen Research PTY Ltd.		
		WO	04/039327 A2	05/13/2004	Colorado State University Research Foundation, Brigham Young University; Children's Hospital Medical Center		

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s) volume-issue number(s), publisher, city and/or country where published.	T ²
/PEZ/		LUND, TD et al., Equol is a Novel Anti-Androgen that Inhibits Prostate Growth and Hormone Feedback, Biol. Reprod., 2004 Apr; 70(4) 1188-95, E-Pub. 2003 Dec. 17	
↓		LUND, T. D., The Phytoestrogen Metabolite Equol Acts as a Novel Anti-Androgen to Inhibit Prostate Growth and Hormone Feedback; Abstract Published for Endo 2003 Program; Endocrine Society 85 th Annual	Abstract
		LUND, T.D., Altered Sexually Dimorphic Nucleus of the Preoptic Area (SDN-POA) Volume in Adult Long-Evans Rats by Dietary Soy Phytoestrogens; Brain Research, Vol. 914, Issues 1-2,-	Abstract
		SETCHELL, Kenneth D.R. et al. Bioavailability of Pure Isoflavones In Healthy Humans and Analysis of Commercial Soy Isoflavone Supplements, American Society for Nutritional Sciences, 2001, pgs. 1362S-1375S	
		SETCHELL, Kenneth D.R. et al., Evidence for lack of absorption of soy isoflavone glycosides in humans, supporting the crucial role of intestinal metabolism for bioavailability, Am J Clin Nutri 2002, 76, pgs. 447-453	
		SETCHELL, KDR et al., Nonsteroidal estrogens of dietary origin: possible roles in hormone-dependent disease, The American Journal of Clinical Nutrition 40, 09/1984, pgs. 569-578	
		SETCHELL, K.D.R. et al., Dietary Phytoestrogens and Their Effect on Bone: Evidence from In Vitro and In Vivo, Human Observational, and Dietary Intervention Studies, Am J Clin Nutr, 2003; 78 (suppl): 593S-609S	
		SETCHELL, K.D.R. et al., Bioavailability, Disposition, and Dose-Response Effects of Soy Isoflavones When Consumed by Healthy Women at Physiologically Typical Dietary Intakes, American Society for Nutritional Sciences, 2003, pgs. 1027-1035	
		SETCHELL, K.D.R. et al., The Clinical Importance of the Metabolite Equol - A Clue to the Effectiveness of Soy and Its Isoflavones, American Society for Nutritional Sciences, 2002, pgs. 3577-3584	
		SETCHELL, Kenneth, D.R. et al. Phytoestrogens: The Biochemistry, Physiology, and Implications for Human Health of Soy Isoflavones, Am J. Clin Nutri 1998, Pgs. 1333S-1346S	
		SETCHELL, K.D.R., et al. S-Equol, a Potent Ligand for Estrogen Receptor β , is the Exclusive Enantiomeric Form of the Soy Isoflavone Metabolite Produced by Human Intestinal Bacterial Flora, The American Journal of Clinical Nutrition, May 2005, Vol. 81, No. 5, 1072-1079	
		SETCHELL, K. D. R., Equol-Its unique Property as a Selective Estrogen Receptor Modulator (SERM) and a Selective Androgen Modulator (SAM), Soy & Health 2004, Brugge, Belgium, October 7-8.	Abstract
		BROWN, Nadine M. et al. Animal Models Impacted by Phytoestrogens in Commercial Chow: Implications for Pathways Influenced by Hormones, Laboratory Investigation, May 2001, Vol. 81, No. 5, pgs. 735-747	Abstract
		LEPHART, E.D., Brain α -Reductase: Cellular, Enzymatic, and Molecular Perspectives and Implications for Biological Function. Molecular and Cellular Neurosciences, 1993(4): p. 473-484	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Complete if Known

Application Number	10/533,045
I.A. Filing Date	03/29/2003
First Named Inventor	LEPHART et al.
Art Unit	1617
Examiner Name	
Attorney Docket Number	CSU-001M

Sheet	4	of	7
-------	---	----	---

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.†	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s) volume-issue number(s), publisher, city and/or country where published.	T²
/PEZ/		LEPHART, E.D., T.D. Lund, and T.L. Horvath, Brain androgen and progesterone metabolizing enzymes: biosynthesis, distribution and function. Brain Res Brain Res Rev, 2001. 37(1-3): p. 25-37	
		LEPHART, E.D., et al., Neurobehavioral effects of dietary soy phytoestrogens. Neurotoxicol Teratol, 2002. 24(1): p. 5-16	
		LEPHART, E.D., Estrogens and Phytoestrogens: Brain Plasticity of Sexually Dimorphic Brain Volumes, J. Steroid Biochem Mol Biol. 2003 Jun; 85(2-5):299-309	Abstract
		LEPHART, E.D., Dietary Soy Phytoestrogen Effects on Brain Structure and Aromatase in Long-Evans Rats, NeuroReport, November, 16, 2001, 12(16):3451-3455	Abstract
		LEPHART, E.D., Behavioral Effects of Endocrine-Disrupting Substances: Phytoestrogens, IJAR J. 2004, 45(4):443-54	
		LEPHART, E.D., Dietary Isoflavones Alter Regulatory Behaviors, Metabolic Hormones and Neuroendocrine Function in Long-Evans Male Rats, Nutrition & Metabolism 2004, 1:16, page 1-14	
		LEPHART, E. D., Equol Reduces Prostate Size and Tail Skin Temperature in Male Rats, Experimental Biology 2005, April 2-6 San Diego, CA, Abstract #280.9	Abstract
		LEPHART, E. D. Antiaging Effects of Equol: A Unique Antiandrogenic Isoflavone Metabolite and its Influence in Stimulating Collagen Deposition in Human Dermal Monolayer Fibroblasts, American Academy of Dermatology, 63 rd Annual Meeting, February 18-22, 2005, New Orleans, LA Vol. 52 No. 3 P1005.	Abstract
		LEPHART, E.D. Equol: A Unique Anti-Androgenic Isoflavone Metabolite Stimulates Collagen (I & III), Elastin and Human Fibroblast Proliferation and Inhibits MMPs and Elastase in 3-D Cultures via FACS Analysis; Published September 28, 2005.	
		WEBER, K. S., Dietary Soy-Phytoestrogens Decrease Testosterone Levels and Prostate Weight Without Altering LH, Prostate 5 α -reductase or Testicular Steroidogenic Acute Regulatory Peptide Levels in Adult Male Sprague-Dawley Rats, Journal of Endocrinology (2001) 170, 591-599 p. 591-599	
		ADLERCREUTZ, H., et al., Dietary phytoestrogens and cancer: in vitro and in vivo studies. J Steroid Biochem Mol Biol, 1992. 41(3-8): p. 331-7	
		ADLERCREUTZ, H., et al., Dietary phyto-oestrogens and the menopause in Japan. Lancet, 1992. 339(8803): p. 1233	
		ADLERCREUTZ, H., et al., Effect of dietary components, including lignans and phytoestrogens, on enterohepatic circulation and liver metabolism of estrogens and on sex hormone binding globulin (SHBG). J Steroid Biochem, 1987. 27(4-6): p. 1135-44	
		ADLERCREUTZ, H., Y. Mousavi, and K. Hockerstedt, Diet and breast cancer. Acta Oncol, 1992. 31(2): p. 175-81	
		ADLERCREUTZ, H. et al, Determination of Urinary Lignans And Phytoestrogen Metabolites, Potential Antiestrogen and Anticarcinogens in Urine of Women on Various Habitual Diets, J. Steroid Biochem, Vol. 25, pp 791-797 (1996)	Abstract
		AKAZA, H., et al., Is daidzein non-metabolizer a high risk for prostate cancer? A case-controlled study of serum soybean isoflavone concentration. Jpn J Clin Oncol, 2002. 32(8): p. 296-300	
		ALBERT, A., et al., Efficacy and safety of a phytoestrogen preparation derived from Glycine max (L.) Merr in climacteric symptomatology: a multicentric, open, prospective and non-randomized trial. Phytomedicine, 2002. 9(2): p. 85-92	
		ALVIRA, E. et al., Molecular modeling study for chiral separation of equol enantiomers by β -cyclodextrin, Chemical Physics 240 (1999), pgs. 101-108, Elsevier Science B.V.	
		ANDERSON, Edith L. et al., The Identification of Equol as 7-Hydroxy-3-(4'-Hydroxyphenyl) Chroman, and the Synthesis of Racemic Equol Methyl Ether, J. Biol. Chem. 127: 649-56 (1939)	
		ATKINSON, C. et al, In Vitro Incubation of Human Feces with Daidzein and Antibiotics Suggests Interindividual Differences in the Bacteria Responsible for Equol Production, Amer. Society for Nutritional Sciences, 134:596-599, March 2004	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Complete if Known

Application Number	10/533,045
I.A. Filing Date	03/29/2003
First Named Inventor	LEPHART et al.
Art Unit	1617
Examiner Name	
Attorney Docket Number	CSU-001M

Sheet 5 of 7

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s) volume-issue number(s), publisher, city and/or country where published.	T2
/PEZ/		AXELSON, M. et al., The Identification of the Weak Oestrogen Equol [7-hydroxy-3-(4'-hydroxyphenyl)chroman] in Human Urine, Biochem. J. 1982, 201, 353-357, Printed in Great Britain	
		AXELSON, M., et al., Soya--a dietary source of the non-steroidal oestrogen equol in man and animals. J Endocrinol, 1984. 102(1): p. 49-56	
		BOWEY, E. et al., Metabolism of Isoflavones and Lignans by the Gut Microflora: a Study in Germ-Free and Human Flora Associated Rats, Food Chem Toxicol., 2003 May; 41 (5): 631-6	Abstract
		CASSIDY, A., Physiological effects of phyto-oestrogens in relation to cancer and other human health risks. Proc Nutr Soc, 1996. 55(1B): p. 399-417	
		CASSIDY, A., S. Bingham, and K. Setchell, Biological effects of isoflavones in young women: importance of the chemical composition of soyabean products. Br J Nutr, 1995. 74(4): p. 587-601	
		DUNCAN, A. M. et al., Premenopausal Equol Excretors Show Plasma Hormone Profiles Associated with Lowered Risk of Breast Cancer, Cancer Epidemiol, Biomarkers Prev Vol. 9: 581-586. June, 2000.	
		GAMBACCIANI, M., et al., Effects of low-dose, continuous combined estradiol and norethisterone acetate on menopausal quality of life in early postmenopausal women. Maturitas, 2003. 44(2): p. 157-63	
		GARREAU, B., et al., Phytoestrogens: new ligands for rat and human alpha-fetoprotein. Biochim Biophys Acta, 1991. 1094(3): p. 339-45	
		GIRI, A.K. and L.J. Lu, Genetic damage and the inhibition of 7,12-dimethylbenz[a]anthracene-induced genetic damage by the phytoestrogens, genistein and daidzein, in female ICR mice. Cancer Lett, 1995. 95(1-2): p. 125-33	
		GOLDIN, B.R. and S.L. Gorbach, Phytoestrogens: possible role in preventing human disease. Nutrition, 1996. 12(3): p. 216-7.	
		HARTLEY, D.E., et al., The soya isoflavone content of rat diet can increase anxiety and stress hormone release in the male rat. Psychopharmacology (Berl), 2003. 167(1): p. 46-53	
		HAVSTEEN, B., Flavonoids, a class of natural products of high pharmacological potency. Biochem Pharmacol, 1983. 32(7): p. 1141-8	
		HEDLUND, T.E., W.U. Johannes, and G.J. Miller, Soy isoflavonoid equol modulates the growth of benign and malignant prostatic epithelial cells in vitro. Prostate, 2003. 54(1): p. 68-78.	
		HWANG, J. et al., The Phytoestrogen Equol Increases Nitric Oxide Availability by Inhibiting Superoxide Production: An Antioxidant Mechanism for Cell-Mediated LDL Modification, Free Radical Biology & Medicine, Vol. 34, No. 10, pp. 1271-1282, (2003)	
		KAO, P.C. and K. P'Eng F, How to reduce the risk factors of osteoporosis in Asia. Zhonghua Yi Xue Za Zhi (Taipei), 1995. 55(3): p. 209-13	
		KAZIRO R. et al., The Oestrogenicity of Equol in sheep, J Endocrinol, 1984 Dec; 103(3): 395-9	
		KINJO, J., Phytoestrogens. Japanese Journal of Clinical Medicine, December 2000, 58(12), pp. 2434-8.	Abstract
		KOHLI, J.C. et al., Specific separation of equol from estrogens by thin-layer chromatography, Journal of Chromatography, 129 (1976), pgs. 473-474, Elsevier Scientific Publ. Co., Amsterdam	
		KOSTELAC, D., G. Rechkemmer, and K. Briviba, Phytoestrogens modulate binding response of estrogen receptors alpha and beta to the estrogen response element. J Agric Food Chem, 2003. 51(26): p. 7632-5	
		LAMARTINIERE, C.A., et al., Daidzein: bioavailability, potential for reproductive toxicity, and breast cancer chemoprevention in female rats. Toxicol Sci, 2002. 65(2): p. 228-38	
		LAMBERTON, John A. et al., Catalytic Hydrogenation of Isoflavones. The Preparation of (±)-Equol and Related Isoflavans, Aust. J. Chem., 1978, pgs. 455-457	
		LANDSTROM, M., et al., Inhibitory effects of soy and rye diets on the development of Dunning R3327 prostate adenocarcinoma in rats. Prostate, 1998. 36(3): p. 151-61.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

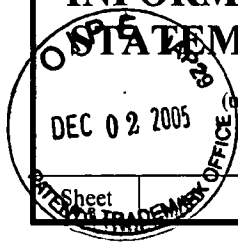
Complete if Known

Sheet	6	of	7	Application Number	10/533,045
				I.A. Filing Date	03/29/2003
				First Named Inventor	LEPHART et al.
				Art Unit	1617
				Examiner Name	
				Attorney Docket Number	CSU-001M

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.†	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s) volume-issue number(s), publisher, city and/or country where published.	T ²
/PEZ/		LU, L.J., et al., Effects of soya consumption for one month on steroid hormones in premenopausal women: implications for breast cancer risk reduction. Cancer Epidemiol Biomarkers Prev, 1996. 5(1): p. 63-70	Abstract
		LYN-COOK, B.D., et al., Methylation profile and amplification of proto-oncogenes in rat pancreas induced with phytoestrogens. Proc Soc Exp Biol Med, 1995. 208(1): p. 116-9	Abstract
		MARTIN, M.E., et al., Interactions between phytoestrogens and human sex steroid binding protein. Life Sci, 1996. 58(5): p. 429-36	
		MITCHELL, J.H., S.J. Duthie, and A.R. Collins, Effects of phytoestrogens on growth and DNA integrity in human prostate tumor cell lines: PC-3 and LNCaP. Nutr Cancer, 2000. 38(2): p. 223-8	
		MORITO, K., et al., Interaction of phytoestrogens with estrogen receptors alpha and beta. Biol Pharm Bull, 2001. 24(4): p. 351-6	
		MURKIES, A.L., et al., Dietary flour supplementation decreases post-menopausal hot flushes: effect of soy and wheat. Maturitas, 1995. 21(3): p. 189-95	
		MUTHYALA, R.S., et al., Equol, a natural estrogenic metabolite from soy isoflavones: convenient preparation and resolution of R- and S-equols and their differing binding and biological activity through estrogen receptors alpha and beta. Bioorg Med Chem, 2004. 12(6): p. 1559-67	
		NAIM, M., et al., Antioxidative and antihemolytic activities of soybean isoflavones. J Agric Food Chem, 1976. 24(6): p. 1174-7.	
		OGAWARA, H., A specific Inhibitor for Tyrosine Protein Kinase from Pseudomonas, The Journal of Antibiotics, Apr. 1936 Vol 39(4) p. 606-608	
		OHTA, Atsutane et al., A combination of Dietary Fructooligosaccharides and Isoflavone Conjugates Increases Femoral Bone Mineral Density and Equol Production in Ovariectomized Mice, American Society for Nutritional Sciences, 2002, pgs. 2048-2054	
		RAFII, F. et al., Variations in Metabolism of the Soy Isoflavonoid Daidzen by Human Intestinal Microfloras from Different Individuals, Arch Microbiol., 2003 Jul; 180(1): 11-6, Epub 2003 May 29.	Abstract
		RIMBACH, G., et al., Antioxidant and free radical scavenging activity of isoflavone metabolites. Xenobiotica, 2003. 33(9): p. 913-25	Abstract
		ROWLAND, I.R., et al., Interindividual Variation in Metabolism of Soy Isoflavones and Lignans: Influence of Habitual Diet on Equol Production by the Gut Microflora, Nutr Cancer, 2000; 36(1): 27-32	
		SATHYAMOORTHY, N. et al., Differential Effects of Dietary Phyto-oestrogens Daidzein and Equol on Human Breast Cancer MCF-7 Cells, European Journal of Cancer, Volume 33, Issue 14, December 1997, Pages 2384-2389	Abstract
		SHARMA, O.P., et al., Soy of dietary source plays a preventive role against the pathogenesis of prostatitis in rats. J Steroid Biochem Mol Biol, 1992. 43(6): p. 557-64	Abstract
		SHARPE, R.M. and N.E. Skakkebaek, Are oestrogens involved in falling sperm counts and disorders of the male reproductive tract? Lancet, 1993. 341(8857): p. 1392-5	
		Sigma-Aldrich webpage, (±)-Equol, Product No. 45405, October 23, 2003	
		Sigma-Aldrich webpage, Equol, Product No. 45405, July 10, 2003	
		SPINOZZI, F., et al., The natural tyrosine kinase inhibitor genistein produces cell cycle arrest and apoptosis in Jurkat T-leukemia cells. Leuk Res, 1994. 18(6): p. 431-9	
		THOMPSON, M.A. et al., Characterization of the Estrogenic Properties of A Nonsteroidal Estrogen, Equol, Extracted from Urine of Pregnant Macaques Biol Reprod, Nov 1984; 31: 705 - 713.	
		WAHALA, Kristina et al., Synthesis of the [³ H] - Labeled Urinary Lignans, Enterolactone and Enterodiol, and the Phytoestrogen Daidzein and its Metabolites Equol and O-Demethyl-angolensin, J. Chem. Soc. Perkin Trans. I, 1986, pgs. 95-98.	
		WHITEHEAD, M., Treatments for menopausal and post-menopausal problems: present and future. Baillieres Clin Obstet Gynaecol, 1996. 10(3): p. 515-30	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				<i>Complete if Known</i>	
				Application Number	10/533,045
				I.A. Filing Date	03/29/2003
				First Named Inventor	LEPHART et al.
				Art Unit	1617
				Examiner Name	
Attorney Docket Number	CSU-001M				
Sheet	1	of	7		



OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
/PEZ/		WIDYARINI S. et al., Isoflavonoid Compounds from Red Clover (Trifolium Pratense) Protect from Inflammation and Immune Suppression Induced by UV Radiation, photochem Photobiol, 2001 Sep; 74(3): 465-70	

Examiner Signature	/Paul Zarek/	Date Considered	08/11/2008
--------------------	--------------	-----------------	------------



Attorney Docket No. CSU-001M

COPENDING U.S. PATENT APPLICATIONS

Examiner Initials*	Applicant(s)	Serial No.	Filing Date	Atty. Docket No.
/PEZ/	Lephart, et al	11/059,951	02/17/2005	CSU-002M
/PEZ/	Setchell, et al.	10/625,989	07/24/2003	CHM-013M2
/PEZ/	Setchell, et al.	10/625,934	07/24/2003	CHM-013M1